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## **SUMMARY STATEMENT OF SAFETY and EFFECTIVENESS**

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In accordance with the provisions of the Safe Medical Device Act of 1990, Aspect Electronics, Inc. is providing a summary of safety and effectiveness information regarding the Aspect Opticam Film Recorder, Multi Format Camera.

### **General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use, indications for use and cautions.

The hardware components of the Aspect Opticam are mainly off-the-shelf computer components that have IEC 601 certification. The unit itself currently has the CSA Mark. The computer equipment complies with part 18 of the FCC rules.

### **Validation of Effectiveness**

Extensive testing of the device has been performed by programmers, by non-programmers and by potential customers. Software used in the device is only used for control purposes and has no bearing on image quality. There is no image processing or compression used with this device. Image quality of the device has been validated by radiologists who compared hard copy images with the original CRT.

### **Substantial Equivalence**

The Aspect Electronics, Inc. Opticam is a multi format camera used for retrieving medical images stored on magneto optical disk (removable media) and makes monochrome 8" x 10" film copies in a six on one format. It also passes color images to color film recorders via a SCSI bus. The intended use and technological characteristics of the system are similar to the Camtronics Ltd, MultiCam System 2200. Any differences between the Aspect Opticam System and the equivalent device have no significant influence on safety or effectiveness.

It is our conclusion that there is no hardware device or software component that we know of in the Aspect Opticam System whose failure or latent system design flaw would be expected to result in death or injury to a patient.